PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT 03 DEC 2004

To:

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Sent by fax in advance

Date of mailing *(day/month/year)*	03.11.2004

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
ISH/P104001	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/01586	14.04.2003	16.04.2002

Applicant
FUTURA MEDICAL DEVELOPMENTS LIMITED

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Tsogka, P Tel. +49 30 25901-727

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ISH/P104001	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/01586	International filing date *(day/month/year)* 14.04.2003	Priority date *(day/month/year)* 16.04.2002
International Patent Classification (IPC) or both national classification and IPC A61F6/04		
Applicant FUTURA MEDICAL DEVELOPMENTS LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
12.11.2003	03.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Kuehne, H-C Telephone No. +49 30 25901-579

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/01586

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-6 as originally filed

Claims, Numbers

1-10 received on 13.10.2004 with letter of 13.10.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-10
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: WO 02/00240 A (QUALILIFE PHARMACEUT INC) 3 January 2002 (2002-01-03)

D1 which is considered to represent the most relevant state of the art discloses (see page 7, lines 24-27) compositions and methods for treating females sexual response by administering to the vagina a vasodilator composition in combination with lubricant as a wet film or coating on the exterior surface of a male condom.

The subject-matter of claim 1 differs from this known D1 in that the vasodilator compound is disposed on the external condom surface in a form or within a composition which is immiscible with the lubricant.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as the translocation of the vasodilator active compound from the external surface of the condom when it is in its rolled-up state for packaging purposes (page 2, paragraph 1 of the application).

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

This solution is not obvious. None of the documents cited in the search reports hints to such a solution. Even though D1 discloses libraries of vasodilator active compounds (page 1, line 21 -page 6, line 23), of "pharmaceutically acceptable carrier" (also used as lubricants; page 8, line 14 - page 9, line 25) and pharmaceutical forms (page 6, lines 30 and 31) this document do not hint to a solution of claim 1, since the synergetic effect of using a combination of a vasodilator active compound which is immiscible with the lubricant is neither explicitly nor implicitly disclosed in D1.

Claims 2-10 are dependent on claim 1 and as such also meet the requirements of the PCT

with respect to novelty, inventive step and industrial applicability.

Claims

1. A condom having applied to its external surface a vasodilator active compound and being coated with a lubricant, characterised in that the vasodilator active compound is disposed on the external condom surface in a form or within a composition which is immiscible with the lubricant.

2. A condom according to claim 1, in which the vasodilator active compound is disposed towards the open end of the condom.

3. A condom according to claim 1 or claim 2, in which the active compound is applied as a composition which includes a carrier material with which the vasodilator compound is miscible but which will release the vasodilator active compound when in contact with body tissue.

4. A condom according to any preceding claim, in which the lubricant is buffered to a pH between 3 and 5.

5. A condom according to any preceding claim, in which the condom includes a textured or undulating region to the external surface.

6. A condom according to claim 5, in which the textured or undulating region extends at least towards the open end of the condom and incorporates or includes the vasodilator active compound.

7. A condom according to claim 6, in which the textured or undulating region is formed from one or more layers of material including the material from which the condom itself is formed, the material of at least one such layer being miscible with the vasodilator and allowing the vasodilator to be absorbed by skin or tissue when brought in contact with the condom.

8. A condom according to any preceding claim, in which the vasodilator active compound is selected from nitrates, long and short acting alpha-adrenoceptor blockers, ergot alkaloids, anti-hypertensives, the prostaglandins and phosphodiesterase inhibitors optionally in combination with a skin penetration enhancer.

9. A condom according to claim 8, in which the vasodilator active compound comprises an organic nitrate applied as a layer or coating in a polar elastomer in solution, in the form of an aqueous dispersion of latex or by a hot melt or reactive process.

10. A condom according to any preceding claim, in which the active compound optionally together with a skin penetration enhancer is applied to the condom as a composition dispersed or dissolved in a gel carrier comprising a liquid medium and a thickening agent.